ACCA INTERNATIONAL

1035

Statement on the Food and Drug Administration's
Proposed Regulations on Prior Notification of Imported Food
Docket Numbers 02N-0278and [redacted]
March 21, 2003

This statement is submitted by the Air Courier Conference of America (ACCA), in response to the *Federal Register* notice in which the Food and Drug Administration (FDA) proposes regulations requiring prior notification of imported food as authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (docket numbers 02N-0278 and 02N-0276). ACCA is the trade association representing the express delivery services industry; its members include large firms with global delivery networks, such as Airborne Express, DHL Worldwide Express, Federal Express, TNT U.S.A. Inc. and United Parcel Service, as well as smaller businesses with strong regional delivery networks, such as International Bonded Couriers, Midnite Express and World Distribution Services. Together, our members employ approximately 510,000 American workers. Worldwide, ACCA members have operations in over 200 countries; move more than 20 million packages each day; employ more than 800,000 people; operate 1,200 aircraft; and earn revenues in excess of $50 billion annually.

ACCA supports the FDA's mission to protect the nation's food supply. We look forward to working with the FDA to achieve the goals outlined by the Bioterrorism Act while preserving and protecting the flow of trade into the United States. The air express industry plays a crucial role in the importation of goods and the international supply chain. We operate in a very time-sensitive environment where packages may be shipped in a matter of a few hours to keep critical industries functioning. The integrated services we provide include not only transportation and customs brokerage, but we also act as the agent for the vast majority of our customers in import matters, including FDA clearance. The proposed regulations affect express operators as much as the actual importer since we often serve as the importer's agent and therefore are the interface with FDA. Consequently, the FDA should consider the scope and impact of any procedures and their effect on the express industry when adopting regulations to implement the requirement for prior notification.

The FDA's proposal to establish prior notification of food products by noon of the calendar day prior to arrival would dramatically affect the international express services our members offer as well as the thousands of companies that rely on our services to stay in business and remain competitive in the global economy. Imposing stricter reporting requirements than exist today would be detrimental to the express industry and our customers. It appears the FDA's objective with the proposed regulation is twofold: first, to meet the statutory deadline; and, second, to facilitate product tracking of the actual U.S. importer or consignee. As discussed below, the express industry already complies

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with the intent of the new regulation absent any new specific prior notification requirement.

Our current practice is to hold food shipments intact either at the initial port of entry or the final port of destination pending the FDA's approval and authorization to deliver the shipment to the importer or consignee. Due to the critical nature of our business, the information required to be submitted for food products in the FDA's OASIS system is already submitted as early as possible prior to arrival.

Since advance notice is already provided through declarations filed in the OASIS system, creating a new, web-based system would be redundant and counterproductive. Furthermore, the amount of information that would be required under the proposed regulation is excessive and, from ACCA's perspective, not absolutely critical for determining whether to inspect or track a shipment. The information currently presented in OASIS is sufficient in this regard, and the proposed regulation would not significantly improve security. Should additional data elements be required, enhancements to OASIS would be more practical, and consistent with current procedures -- rather than creating an entirely new reporting system, which would also not be interfaced with either OASIS or ABI. For all these reasons, we strongly urge the FDA to utilize OASIS for the required prior notice declaration.

In the express industry, tight controls are in place throughout the entire transportation process to ensure the security of packages and to guard against unauthorized delivery to the importer or consignee prior to proper clearance by relevant government agencies. ACCA and its members have collaborated extensively with U.S. Customs and the Transportation Security Administration to develop procedures that achieve security objectives. Moreover, we provide Customs the most detailed and automated shipment data of any mode of transportation. This data is filed in advance of the aircraft arrival and is available for use by the FDA.

The FDA outlined five options that are being considered under the proposed regulations. For the reasons provided above, ACCA does not believe any of these options should be implemented.

The proposed regulations specifically mention some exemptions to the prior notification requirements; namely, food products carried by individuals entering the U.S. as part of the individual's personal baggage that are intended for personal use. We assume this exemption also applies to shipments of food products imported via common carriage that are part of an individual's unaccompanied baggage that are intended for personal use. Food products entering the country whether imported via a common carrier or as part of accompanied baggage entering with the individual should be treated the same. The proposed regulations should clarify this issue and contain specific language to this effect. Further, small shipments of nominal value for personal, non-commercial use should be similarly exempted from the requirement for prior notification. The express industry handles thousands of such shipments now, which include purchases from a growing number of Internet-based sellers. Small shipments of this type for personal use

hardly qualify as a risk to the domestic food supply, and should therefore be considered outside the scope of the requirement for prior notification.

The proposed regulations also fail to establish a value threshold for shipments subject to the prior notice mandate. Submitting prior notices for shipments of *de minimis* value (i.e., less than $200) would not benefit the FDA or the trade. A *de minimis* rule consistent with that of U.S. Customs should be established, and such shipments should be exempted from the prior notification requirement.

Subpart 1.276 of the proposed regulations identifies the imported foods that are subject to the new requirement, and includes shipments that will be immediately exported from the port of entry and transshipments through the United States to other countries. ACCA is concerned that the FDA would require the submission of prior notifications for transit shipments. In the express industry, there are tens of thousands of such shipments, and more importantly, in the vast majority of cases transit shipments do not remain in the country longer than 24 hours. During the brief time the shipments are in the country, they are under the strict control of the express operator. It is highly unlikely that any of these shipments would be inadvertently delivered in the United States. Submitting prior notifications for transit food shipments would present a tremendous burden for our industry, requiring substantial procedural and process changes that would be very costly for the industry to implement. It is unclear how prior notifications for transit shipments would benefit the FDA or reduce the threat to public health, and we urge the FDA to exclude these shipments from the scope of the new regulations.

An additional concern is the draft's statement that "any information that would disclose the identity or location of a specific registered person is not subject to disclosure (to the public)." Unless there is some reference database available to traders, it could be quite difficult to comply with the regulation. If the registration number must be submitted, a universal database must be available for all to review.

ACCA is also troubled by the draft's proposal that, "when mixed consolidated freight contains articles of food that must be held at the port of entry those articles must be dealt with before the rest of the shipment proceeds." This could wreak havoc with shipping schedules in the express industry, and is simply not justified. Non-food commodities, and commodities not regulated by FDA, should not be delayed for FDA processing of regulated articles.

ACCA is also quite concerned about the FDA's ability to support this new mandate from a staffing perspective. Unless FDA can have staff available 24/7 to answer questions and to process the additional declarations submitted in the OASIS system, implementing the regulation would significantly impede the flow of commerce.

Our final comment regarding the proposed regulations relates to the definition of a "holding" facility for imported food articles, which would be required to register with FDA. The definition of "holding" as proposed would not include carrier facilities that merely "hold" or stage goods as an incidental occurrence to the transportation from a

shipper to a consignee. Such delay may occur for a variety of reasons, for example, while FDA clearance is in process, or while the shipment simply awaits transfer to another carrier. "Holding" or storage is distinctly different from transportation, and is clearly not part of an express carrier's transportation offering. A "holding" facility would clearly be defined as owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, storing, or warehousing food for consumption, and would therefore not include a carrier providing transportation services. We recommend that the proposal be revised as follows to clarify these issues:

- Add a new subsection 1.226(h) as follows:
  "1.226(h): Air, ocean, or surface transportation companies providing transportation and related services for import to the United States. "Holding" or "manufacturing/processing" activities as defined in part 1.227 would require registration."

- Add the following sentence to 1.227(5):
  "The temporary staging in a carrier's facility of a shipment in transit from a shipper to a consignee which is incidental to the transportation is not holding or storage for purposes of this definition."

In conclusion, ACCA strongly supports efforts to improve security of the U.S. food supply and to enhance the security of the international trade supply chain by adopting practical measures that also recognize trade facilitation requirements. We recommend that the FDA and ACCA meet to discuss the issues identified herein, and to discuss a mutually acceptable approach for providing prior notice for food shipments to the FDA that satisfies the intent of the new regulations while minimizing the impact to the express industry and our customers. To schedule a meeting, please contact Sue Presti, Executive Director of ACCA-International, at 703-998-7121 or spresti@erols.com. We appreciate the FDA's consideration of these comments.